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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/277,401	03/26/99	JAYE	22944-USA

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1101 MARKET STREET
PHILADELPHIA PA 19107

HM12/0814

EXAMINER

TUNG, F

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 08/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary

Application No.

09/277,401

Applicant(s)

Jaye et al.

Examiner

Peter Tung

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on May 29, 2001

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1, 7, 8, 10, 13-16, 19-25, 28-32, 34, 37, 39-41, 43-47, 49-53, 54 is/are pending in the application.

4a) Of the above, claim(s) Please see Office action is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 20, 66-72, and 77-84 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3

20) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Claims 1, 7, 8, 10, 11, 13-16, 19-25, 28-32, 34, 35, 37, 39-41, 43-47, 49-53, 55-59 and 63-84 are pending. Claims 1, 7, 8, 10, 11, 13-16, 19, 21-25, 28-32, 34, 35, 37, 39-41, 43-47, 49-53, 55-59 and 63-65 and 73-76 are withdrawn from further consideration as being drawn to a non-elected invention. Claims 20, 66-72 and 77-84 will be examined on the merits.

Claim Objections

2. Claim 80 is objected to because of the following informalities: phosphate is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 20, 66-72 and 74-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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5. The term "pharmaceutical composition" in claim 20 is a relative term which renders the claim indefinite. The term "pharmaceutical composition" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The instant disclosure does not provide for a pharmaceutical composition comprising an LIPG polypeptide as the use of such a polypeptide in a pharmaceutical composition is not recognized in the art. This rejection may be overcome by removing "pharmaceutical" from the claim.

6. Claims 77 and 84 are indefinite as they refer to a composition for pharmaceutical use. The instant disclosure does not provide for a pharmaceutical composition comprising an LIPG polypeptide as the use of such a polypeptide in a pharmaceutical composition is not recognized in the art.

7. Claims 20, 66-72 and 74-84 are indefinite as "LIPG" is not defined. What "LIPG" represents should be spelled out in the claim to first mention "LIPG" (claim 20).

8. Claim 80 is indefinite as the biologically-compatible solution comprises a Markush group consisting of buffer compounds. These compounds are used to make aqueous buffers and a biologically-compatible solution would comprise these buffer compounds.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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10. Claims 20, 66-72 and 77-84 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polypeptides of SEQ ID NOS: 6, 8 and 10, does not reasonably provide enablement for any LIPG polypeptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The breadth of the claims encompass an LIPG polypeptide. As defined in the specification, such an LIPG polypeptide could be any triacylglycerol lipase. However, insufficient guidance and examples are provided on an LIPG polypeptide other than those of SEQ ID NOS: 6, 8 and 10. As there is unpredictability in the art in obtaining lipases without sufficient guidance on how to purify the enzyme or providing the DNA sequence which encodes the protein, the skill of those in the art is low in making LIPG polypeptide besides those disclosed by SEQ ID NO: in the instant application. Undue experimentation would be required to enable the full scope of the invention based upon the limiting scope of the instant disclosure.

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11. Claims 66-68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The breadth of the claims encompass a compound which enhances the enzymatic activity of LIPG and compounds which specifically enhance the enzymatic activity of LIPG with LDL cholesterol or VLDL cholesterol relative to HDL cholesterol and apo AI. However, insufficient examples and guidance are provided on such activity enhancing compounds. Insufficient examples and guidance are provided on how to make such compounds or what such compounds would be. As there is unpredictability in the art in making compounds which enhance the activity of an enzyme and in particular, an LIPG polypeptide, and such enhancers are not known in the prior art, the skill of those in the art is low in making an enhancer of LIPG enzymatic activity. Undue experimentation would be required to enable the instant claims based upon the instant disclosure.

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12. Claims 74-76 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polypeptides of SEQ ID NO: 6, 8 and 10, does not reasonably provide enablement for a variant of said polypeptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The breadth of the claims encompass a polypeptide comprising any variation in sequence of SEQ ID NO: 6, 8 or 10. Insufficient guidance and examples are provided on how to make and use such variants of said polypeptide sequences. There is unpredictability in the art in making variants of enzymes. The skill of those in the art is low in making and using variants of said polypeptides without sufficient guidance and examples. Undue experimentation would be required to enable the full scope of the invention based upon the limiting scope of the disclosure.

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Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 20, 66-72 and 74-76 are rejected under 35 U.S.C. 102(b) as being anticipated by Cooper et al.

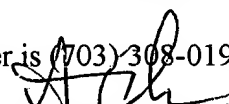
With regard to claims 20 and 66-72, Cooper et al. teach a polypeptide which has lipase activity, which is that of the instant claims.

With regard to claims 74-76, Cooper et al. teach a polypeptide sequence which comprises fragments or a variant of SEQ ID NOS: 6, 8 or 10, which is that of the instant claims.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Tung, Ph.D. whose telephone number is (703) 308-9436. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, Ph.D., can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600


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LIPL_CHICK
ID   LIPL_CHICK      STANDARD;          PRT;   490 AA.
AC   P11602;
DT   01-OCT-1989 (Rel. 12, Created)
DT   01-OCT-1989 (Rel. 12, Last sequence update)
DT   01-FEB-1996 (Rel. 33, Last annotation update)
DE   LIPOPROTEIN LIPASE PRECURSOR (EC 3.1.1.34) (LPL).
OS   Gallus gallus (Chicken).
OC   Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
OC   Archosauria; Aves; Neognathae; Galliformes; Phasianidae; Phasianinae;
OC   Gallus.
OX   NCBI_TaxID=9031;
RN   [1]
RP   SEQUENCE FROM N.A.
RC   STRAIN=LEGHORN CORNELL K; TISSUE=Adipose tissue;
RX   MEDLINE=89247453; PubMed=2719965;
RA   Cooper D.A., Stein J.C., Strielemann P.J., Bensadoun A.;
RT   "Avian adipose lipoprotein lipase: cDNA sequence and reciprocal
RT   regulation of mRNA levels in adipose and heart.";
RL   Biochim. Biophys. Acta 1008:92-101(1989).
RN   [2]
RP   SEQUENCE FROM N.A.
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CC   -----
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DR   EMBL; X14670; CAA32800.1; -.
DR   EMBL; X60547; CAA43037.1; -.

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 CC -----
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 DR EMBL; X14670; CAA32800.1; -.
 DR EMBL; X60547; CAA43037.1; -.

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DR      PIR; S04331; S04331.
DR      PIR; S20598; S20598.
DR      HSSP; P06857; 1RP1.
DR      InterPro; IPR000734; -.
DR      InterPro; IPR001024; -.
DR      InterPro; IPR002330; -.
DR      Pfam; PF01477; PLAT; 1.
DR      Pfam; PF00151; lipase; 1.
DR      PRINTS; PR00821; TAGLIPASE.
DR      PRINTS; PR00822; LIPOLIPASE.
DR      PROSITE; PS00120; LIPASE_SER; 1.
KW      Hydrolase; Plasma; Glycoprotein; Lipid degradation; Chylomicron;
KW      VLDL; Heparin-binding; GPI-anchor; Signal.
FT      SIGNAL          1          25
FT      CHAIN           26        490      LIPOPROTEIN LIPASE.
FT      ACT_SITE       159        159      CHARGE RELAY SYSTEM (BY SIMILARITY).
FT      ACT_SITE       183        183      CHARGE RELAY SYSTEM (BY SIMILARITY).
FT      ACT_SITE       268        268      CHARGE RELAY SYSTEM (BY SIMILARITY).
FT      DOMAIN         319        331      HEPARIN-BINDING (POTENTIAL).
FT      DISULFID        54         67      BY SIMILARITY.
FT      DISULFID       243        266      BY SIMILARITY.
FT      DISULFID       291        310      BY SIMILARITY.
FT      DISULFID       302        305      BY SIMILARITY.
FT      DISULFID       445        465      BY SIMILARITY.
FT      CARBOHYD        70         70      N-LINKED (GLCNAC. . .) (POTENTIAL).
FT      CARBOHYD       386        386      N-LINKED (GLCNAC. . .) (POTENTIAL).
FT      CONFLICT       377        377      P -> A (IN REF. 2).
SQ      SEQUENCE      490 AA;  55132 MW;  C014D23363E81FF3 CRC64;

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Qy	7	LLCFWSLQCYCFAAGSPVFFGPEGRLEDKLHKPKATQTEVKPSPVRFNLRTSKDPHEGECYL	66
Db	12	LLAVLCLCLRGAAGS-----DPEAEMNFEGIESKFSRLTPAEPDEDVCYL	56
Qy	67	SVGHSQPLEDCSFNMTAKTFFIIHGWTMSGIFENWLHLKLVSAHRTREKDANVVVVDWLPL	126
Db	57	VPGQMSLAQC�FNHTSKTFVVIHGWTVTGMYESWVPKLVDALYKREPDSNVIVVDWLVR	116
Qy	127	AHQLYTDAVNNTRVVGHSIARMLDWLQEKDDFSLGNVHLIGYSLGAHVAGYAGNFVKGTV	186
Db	117	AQQHYPVSAAYTKLVGKDVMAMFIDWMEEKFNYPNPNVHLLGYSLGAHAAGIAGSLTKKKV	176
Qy	187	GRITGLDPAGPMFEGADIIHKRLSPDDADFVDVLHTYTR-SFGLSIGIQMPVGHIDIYPNG	245
Db	177	NRITGLDPAGPTFEYADAPIRLSPDDADFVDVLHTYTRGSPDRSIGIQKPVGHIDIYPNG	236
Qy	246	GDFQPGCGLNDVLGSIA---YGTITEVVKCEHERAVHLFVDSLQNDKPSFAFQCTDSNR	302
Db	237	GGFQPGCNLGEALRLIAEKGFSDVDQLVKCSHERSIHLFIDSLLYEEKPSMAYRCNTKEA	296
Qy	303	FKKGICLSKRKNRCNSIGYNAKKMRNKRNSKMYLKTRAGMPFRVYHYQMKIHVFSYKNMG	362
Db	297	FEKGLCLSKRKNRCNNLGKVNVRVTRKNTKMYLKTRAOMPYKVFHYQVKIHFFGKTNTV	356

Qy 363 EIEPTFYVTLYGTNADSQTLPLEIVERIEQNATNTFLVYTEEDLGDLLKIQLTWE-GASQ 421
 ::: | ::||| :|: :| :| : | | :||:| | :||| :| |
 Db 357 KVDQPFLISLYGTLDESENIPFTLPE-VSSNKTFSEFLIYTEVDIGDLLMLKLQWEKDTEFF 415

 Qy 422 SWYNLWKEFRSYLSQPRNPGRELNIRRVKSGETQRKLTFCEDPENTSISPGRE-LWF 480
 || : | | | :|: ||||| :|: ||: | : : | | |
 Db 416 SWSDWWTPF-----AFTIQVRVKSGETQKKVVFCSR-DGSSRLGKGEEAAIF 462

 Qy 481 RKC 483
 ||
 Db 463 VKC 465

LIPL_CHICK

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 DR EMBL; X60547; CAA43037.1; -.

